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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,495	09/29/2004	Reddy Bandi Parthasaradhi	H1089/20014	7773
3000 7590 01/30/2007 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER CHUNG, SUSANNAH LEE	
			ART UNIT	PAPER NUMBER
			1626	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/30/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/509,495

Applicant(s)

PARTHASARADHI ET AL.

Examiner

Susannah Chung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/7/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-5 are pending in the instant application. The supplemental amendment filed on 9/29/2005 is acknowledged.

Priority

This application is a 371 of PCT/IN03/00096, filed 03/31/2003.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 2/7/2005 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Buhlmayer, et al (U.S. Pat. No. 5,399,578 ('578 Patent)).

Applicants claims relate to amorphous valsartan, the process of preparing amorphous valsartan and the pharmaceutical composition of amorphous valsartan. Buhlmayer discloses the valsartan, the process of preparing amorphous valsartan and the pharmaceutical composition of valsartan. Although Buhlmayer does not use the word amorphous to describe the valsartan, the amorphous form of the valsartan is inherent in the disclosure.

MPEP 2112 states that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject

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matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) (“[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.”); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed. Cir. 1999) (“If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics.”); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) (“‘Because sufficient aeration’ was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.”); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound “inherently” anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound “inherently results in at least trace amounts of” the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate).

MPEP 2112 also states that “The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not

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render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

The instant claims are directed to an amorphous form characterized by an x-ray powder diffraction spectrum shown in figure 1. Figure 1 shows a typical x-ray powder diffraction spectrum of an amorphous compound. It is a broad curve close to the baseline, with no sharp or differentiating peaks, which would provide patentable limitations. (See 112 rejections below for further explanation). Therefore, Figure 1 is not considered a patentable limitation of an amorphous form of a compound and Claims 1 and 5 are directed to amorphous valsartan and its pharmaceutical composition, which is inherently taught in the disclosure of the prior art (See ‘578 Patent, claims 1-5).

Claims 2-4 are directed to a process of preparing amorphous valsartan, but do not provide steps in making valsartan rather the steps provided are directed the purification of valsartan. Recovery steps are per se uninventive and must be claimed with other significant steps. See *Ex parte Deutschman and Bull*, 114 USPQ 556. (See rejection below). The ‘578 Patent discloses several methods of making, which include dissolving valsartan in alcohol and drying the compound. (See ‘578 Patent, Examples 1-91, columns 28-62).

Therefore, Claims 1-5 are rejected under 35 USC 102(b) as being anticipated by the ‘578 Patent.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The x-ray powder diffraction spectrum as in figure 1 is not enabled. It is well known in the art that characterizing an amorphous compound is difficult. It is also well known in the art that an x-ray powder diffraction spectrum is an effective measurement tool when there are sharp peaks present and then those peak values are given patentable weight. Amorphous forms of compounds do not have peaks, but are characterized by a broad curve close to the baseline. In essence, there is no peak in the x-ray powder diffraction spectrum and the data obtained does not provide any meaningful information that would distinguish amorphous valsartan from any other amorphous form of a compound. Therefore an x-ray powder diffraction spectrum is not a useful tool in the characterization of amorphous compounds. On the other hand, an x-ray diffraction powder spectrum would provide patentable limitations for crystalline forms of compounds, which are characterized by sharp peaks at different points.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims must stand alone to define the invention and incorporation into claims by express reference to the specification is not permitted. Ex parte Fressola, 27 USPQ 2d 1608.

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Claims that require one to read the specification to determine the metes and bounds of the invention are repugnant to modern practice in the Office and are properly rejected under 35 USC 112, 2nd paragraph, as failing to particularly point out and distinctly claim the invention. Id. At 1609. Claim 1 is drawn an x-ray powder diffraction spectrum as in figure 1. It is not proper to refer to a figure in a claim as claims must stand alone.

Claim Rejections - 35 USC § 101 and 112, 1st paragraph

Claims 2-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. Claims 2-4 are not processes for preparing a compound, rather they are processes for purifying the known compound valsartan. Recovery steps are per se un inventive and must be claimed with other significant steps. See Ex parte Deutschman and Bull, 114 USPQ 556. Claims 2-4 do not add significant steps to the process of preparing valsartan and this is demonstrated by the claims, wherein the process starts and ends with the product valsartan.

Claims 2-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention without an undue amount of experimentation because the steps are indefinite and vague. See 112, 2nd paragraph rejection.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps include, but are not limited to: how is the valsartan of claim 2 obtained and what are the patentable steps of the process for preparing the final valsartan product? In essence, the process is so general and vague that it reads on most processes for preparing valsartan. See 102(b) rejection.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-4 recites the limitation "The process." There is insufficient antecedent basis for this limitation in the claim because the process was not described in Claim 1. Claim 2 should read "A process."

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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